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Section 5: 510(k) Summary:

FEB 1 4 2013

Luofucon Silver Alginate Dressing (Prescription)

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302012
Submitter's FDA Registration Number: 3007735241

US Agent and Contact Person

Chengyu Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: December 14, 2012

Device Name:	
Trade Name:	Luofucon Silver Alginate Dressing (Prescription)
Common Name:	Silver Alginate Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K041316, "Silver Alginate II Dressing", manufactured by "Advanced Medical Solutions, Inc" located in Cheshire, England CW7 3PD
(2) K023612, "Antibacterial Barrier Wound Contact Dressing", manufactured by "Argentum Medical LLC" located in Lakemont, Georgia 30552

Section 5: 510(K) Summary: Prescription

Device description:

Luofucon Silver Alginate Dressing is a sterile, non-woven pad composed of a high G (guluronic acid) calcium alginate and metallic silver particles, which absorbs wound exudate. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The alginate material consists of metallic silver that provides effective protection against microbial contamination of the dressing material. Odour reduction results from the bacteria reduction effect in the dressing.

The dressing has an off-white appearance and is available in the form of pad and in three different sizes (50 mm x 50 mm, 100 mm x 10 mm, 200 mm x 100 mm), packaged in pouches. Additional sizes may also be manufactured per customer request. All dressings have the exactly the same material, chemical, and physical properties and are different only in size.

All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 50ug/100cm^2 silver particles

Intended Use:

Prescription:
Luofucon Silver Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites

Comparison to Predicate Devices

Luofucon Silver Alginate Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K041316, "Silver Alginate II Dressing", manufactured by "Advanced Medical Solutions, Inc" located in Cheshire, England CW7 3PD
(2) K023612, "Antibacterial Barrier Wound Contact Dressing", manufactured by "Argentum Medical LLC" located in Lakemont, Georgia 30552

The following table shows similarities and differences of use, design, material, and processing

methods between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K041316)	Predicate Device 2 (K023612)
Indication for Use	Prescription: Luofucon Silver Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites	Prescription: Same as ours	Prescription: Provide an effective barrier to bacterial penetration and are intended for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic).
Prescription/ OTC	Prescription	Prescription	Prescription and OTC
Mechanism	Silver for antibacterial effect; calcium alginate for exudate absorption and wound care	Same	Silver for antibacterial effect; nylon fabric for wound care
Design/ Material	Calcium alginate and silver	Calcium alginate, carboxymethylcellulose (CMC) and silver	Nylon fabric and silver
Single Use	Yes	Yes	Yes
Sterile	Sterile	Sterile	Sterile

Both Luofucon Silver Alginate Dressing and its predicate device (K041316) utilize calcium alginate for the exudate absorption and wound management. K041316 also has small quantity of carboxymethylcellulose (CMC) while our device does not have. This slight difference is insignificant and does not affect the intended use and performance of the device.

K023612 utilizes nylon fabric for the wound care purpose, which is different from our device and K041316. However, nylon fabric permits fluid passage from wound, and similar to calcium alginate, it also helps maintaining moist environment for optimal wound heal. The difference between our device and K023612 does not change the intended use and performance of the device.

Luofucon Silver Alginate Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Biocompatibility tests were conducted following procedures outlined in the respective consensus

standards, and results for Luofucon Silver Alginate Dressing met all relevant requirements in the test standards, and are comparable to the predicate devices.

Antibacterial activity was measured following AATCC 100-2004 for total of six (three Gram positive and three Gram negative) bacteria to evaluate the broad spectrum antibacterial effectiveness. Luofucon Silver Alginate Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for one day.

The results are comparable to the predicate devices when the dressings are used for antibacterial purpose and changed daily during use. This is clarified in our product labeling.

K041316 has longer antibacterial duration than our product. However, we have specified in the User Instruction that daily changed is required when using our products.

In summary, Luofucon Silver Alginate Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006. The product is safe and effective for its intended use.

AATCC 100-2004 was used to evaluate the antibacterial activity of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum antibacterial effectiveness of the silver alginate dressing.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Alginate Dressing is substantial equivalent to its predicate devices.

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Section 5: 510(k) Summary:

Luofucon Antibacterial Alginate Dressing (OTC)

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302012
Submitter's FDA Registration Number: 3007735241

US Agent and Contact Person

Chengyu Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: December 14, 2012

Device Name:	
Trade Name:	Luofucon Antibacterial Alginate Dressing (OTC)
Common Name:	Silver Alginate Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K041316, "Silver Alginate II Dressing", manufactured by "Advanced Medical Solutions, Inc" located in Cheshire, England CW7 3PD
(2) K023612, "Antibacterial Barrier Wound Contact Dressing", manufactured by "Argentum Medical LLC" located in Lakemont, Georgia 30552

Device description:

Luofucon Antibacterial Alginate Dressing is a sterile, non-woven pad composed of a high G

(guluronic acid) calcium alginate and metallic silver particles, which absorbs wound exudate. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The alginate material consists of metallic silver that provides effective protection against microbial contamination of the dressing material. Odour reduction results from the bacteria reduction effect in the dressing.

The dressing has an off-white appearance and is available in the form of pad and in three different sizes (50 mm x 50 mm, 100 mm x 10 mm, 200 mm x 100 mm), packaged in pouches. Additional sizes may also be manufactured per customer request. All dressings have the exactly the same material, chemical, and physical properties and are different only in size.

All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

Product Information:

Active Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum protection against Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 50ug/100cm^2 silver particles

Intended Use:

OTC: First aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.

Comparison to Predicate Devices

Luofucon Antibacterial Alginate Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K041316, "Silver Alginate II Dressing", manufactured by "Advanced Medical Solutions, Inc" located in Cheshire, England CW7 3PD
(2) K023612, "Antibacterial Barrier Wound Contact Dressing", manufactured by "Argentum Medical LLC" located in Lakemont, Georgia 30552

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K041316)	Predicate Device 2 (K023612)
Indication for Use	OTC: First aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.	OTC: N/A This predicate is a prescription product.	OTC: Same as ours
Prescription/ OTC	OTC	Prescription	Prescription and OTC
Mechanism	Silver provides protection against bacteria; calcium alginate for exudate absorption and wound care	Same	Silver provides protection against bacteria; nylon fabric for wound care
Design/ Material	Calcium alginate and silver	Calcium alginate, carboxymethylcellulose (CMC) and silver	Nylon fabric and silver
Single Use	Yes	Yes	Yes
Sterile	Sterile	Sterile	Sterile

Luofucon Antibacterial Alginate Dressing and its predicate device (K041316) utilize calcium alginate for the exudate absorption and wound management. K041316 also has small quantity of carboxymethylcellulose (CMC) while our device does not have. This slight difference is insignificant and does not affect the intended use and performance of the device.

K023612 utilizes nylon fabric for the wound care purpose, which is different from our device and K041316. However, nylon fabric permits fluid passage from wound, and similar to calcium alginate, it also helps maintaining moist environment for optimal wound heal. The difference between our device and K023612 does not change the intended use and performance of the device.

Luofucon Antibacterial Alginate Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Biocompatibility tests were conducted following procedures outlined in the respective consensus standards, and results for Luofucon Antibacterial Alginate Dressing met all relevant requirements in the test standards, and are comparable to the predicate devices.

Protection against bacteria was measured following AATCC 100-2004 for total of six (three Gram positive and three Gram negative) bacteria to evaluate the broad spectrum effectiveness. Luofucon Antibacterial Alginate Dressing is effective (>99.99% reduction) for all 6 bacteria and effect lasts for one day.

The results are comparable to the predicate devices when the dressings are changed daily during use. This is clarified in our product labeling.

K041316 has longer protection duration than our product. However, we have specified in the User Instruction that daily changed is required when using our products.

In summary, Luofucon Antibacterial Alginate Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006. The product is safe and effective for its intended use.

AATCC 100-2004 was used to evaluate the protection against bacteria of the product. This method only specifies the use of one gram positive bacteria (*Staphylococcus aureus*) and one gram negative bacteria (*Klebsiella pneumoniae*). However, we evaluated total of six (three Gram positive and three Gram negative) bacteria to evaluate broad spectrum effectiveness of this alginate dressing.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Antibacterial Alginate Dressing is substantial equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Huizhou Foryou Medical Devices Company, Limited
% Manton Business and Technology Services
Chengyu Shen
5 Carey Street
Pennington, New Jersey 08534

February 14, 2013

Re: K120181
Trade/Device Name: Luofucon Antibacterial Alginate Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 14, 2012
Received: January 03, 2013

Dear Chengyu Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4: Indication for Use Statement

Luofucon Antibacterial Alginate Dressing (OTC)

510(k) Number (if known): K120181

Device Name: Luofucon Antibacterial Alginate Dressing

Indications for Use:

OTC: First aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X_ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number __K120181_____

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Section 4: Indication for Use Statement

Luofucon Silver Alginate Dressing (Prescription)

510(k) Number (if known): K120181

Device Name: Luofucon Silver Alginate Dressing

Indications for Use:

Prescription:
Luofucon Silver Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number ___K120181_____